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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/675,936	09/30/2003	F. William Studier	BSA 02-29	2367
7590	02/10/2006		EXAMINER	
Margaret C. Bogosian, Esq. Brookhaven Science Associates, LLC Building 375D P.O. Box 5000 Upton, NY 11973-5000			VOGEL, NANCY S	
			ART UNIT	PAPER NUMBER
			1636	
DATE MAILED: 02/10/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/675,936	STUDIER, F. WILLIAM
	Examiner	Art Unit
	Nancy T. Vogel	1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_.
- 2a) This action is **FINAL**.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-40 is/are pending in the application.
  - 4a) Of the above claim(s) 23-39 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_ is/are allowed.
- 6) Claim(s) 1-22 and 40 is/are rejected.
- 7) Claim(s) \_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. ____.
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>see next page</u> .	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: ____.

3. 10/24/05, 6/17/05, 4/18/05, 2/2/04

## **DETAILED ACTION**

Claims 1-40 are pending in the case

Receipt of Information Disclosure statements on 10/24/05, 6/17/05, 4/18/05 and 2/2/04, is acknowledged.

### ***Election/Restrictions***

Claims 23-39 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 12/8/05.

Applicant's election without traverse of Group I, claims 1-22 and 40 in the reply filed on 12/8/05 is acknowledged.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-22 and 40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The rejection is based on the Guidelines for the Examination of Patent Applications under the 35 U.S.C. 112, first paragraph "Written Description published in the Federal Register (Volume 66, Number 4, Pages 1099-1111). Claim 1 is drawn to a method for promoting auto-induction of cloned DNA in any bacterial cell, using any promoter whose activity can be induced by an exogenous inducer whose ability to induce said promoter is dependent on the metabolic state of said bacterial cells, comprising providing any inducer that causes induction of transcription from said promoter, and any metabolite that prevents induction by said inducer, adjusted so as to preclude induction by said inducer in early states of growth, but such that said metabolite is depleted to a level that allows induction by said inducer at a later stage of growth. Claims 2 and 3 specify E. coli cells. Claim 5 specifies the T7lac promoter. Claim 6 specifies the promoter is repressed by the lac repressor. Claims 7-21 and 40, each dependent on claim 1, specify media components. Claim 21 specifies the pH after growth to saturation.

Claims 1-22 and 40 are genus claims in terms of a method using any bacteria, any promoter, using any inducer and any metabolite which prevents induction by said inducer, in any culture medium, and in terms of methods in which one component (i.e. promoter, inducer, metabolite, culture medium or component thereof) is specified with other components broadly claimed. The disclosure is not deemed to be descriptive of the complete structure of a representative number of species encompassed by the claims as one of skill in the art cannot envision all the methods utilizing the encompassed variables (i.e. host cell, promoter, inducer, metabolite, medium

components) based on the teachings of the specification. While the specification provides general information on autoinduction of the expression of a protein of interest in bacterial cells by using appropriately selected promoter systems, culture components, inducers and metabolites which will prevent induction until a later stage of growth is achieved, the provision of guidance for one specific example of such a system, does not provide an adequate description of the entire genus of claimed methods. It is apparent that much experimentation was carried out to arrive at appropriate culture components in the single system utilized in the specification, and generalization to the broad genus of claimed methods cannot be made. Therefore, the specification does not describe the claimed method of promoting auto-induction of transcription in such full, clear, concise and exact terms so as to indicate that Applicant has possession of the method at the time of filing the present application. Thus, the written description requirement has not been satisfied.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-22 and 40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, and by dependence, claims 2-22 and 40, are vague and indefinite in the recitation of the phrases "in the early stages of growth" and "at a later stage of growth".

These phrases are relative and it cannot be clearly determined what is intended.

Therefore the metes and bounds of the intended subject matter cannot be determined.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1- 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Hoffman et al. (Protein Expression and Purification 6, 646-654 (1995) (cited by applicants).

Hoffman et al. disclose a method for promoting auto-induction of transcription of cloned DNA in cultures of *E. coli* strain BL21(DE3), said transcription being under control of the promoter T7lac promoter, wherein a culture medium comprising an inducer which is lactose, and a metabolite which is glucose is added such that the induction is substantially precluded in the early stages of growth of the culture, but such that said metabolite is depleted to a level that allows induction by said inducer at a later stage of growth, inoculating the medium with a bacterial inoculum comprising bacterial cells containing cloned DNA, the transcription of which is induced by said inducer, and incubating the culture under conditions appropriate for growth of the bacterial cells (see abstract, see page 647, first col., first complete paragraph through second column, end of first complete paragraph; see page 648, first column; see page 653, first column, first

complete paragraph). The culture medium may contain a tryptic digest of casein (page 647, first column, last paragraph), glycerol, magnesium cation, phosphate, sulfate, ammonium, sodium, or potassium (page 647, first and second col.).

### ***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy T. Vogel whose telephone number is (571) 272-0780. The examiner can normally be reached on 6:30 - 3:00, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
NANCY VOGEL, Ph.D.  
PATENT EXAMINER